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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,133

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Francesco Sias

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23117

7590

09/04/2008

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EXAMINER

NIA, ALIREZA

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,133	<b>Applicant(s)</b> SIAS, FRANCESCO	
	<b>Examiner</b> ALIREZA NIA	<b>Art Unit</b> 3739	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-35 and 37-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-35 and 37-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 50 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

2. The recitation “the window is positioned beyond the distal end of the first hollow body” in claim 50, is unclear and vague. Beyond the distal end of the first hollow body is space and the claim language is reciting that the window is positioned in space and not positioned on the first hollow body. Therefore, the claim language is rendered indefinite since it is unclear as to where the window is being positioned. The claim is examined as best understood.

3. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. There are no steps of the "Sias" method recited in the claims. The claim is examined as best understood.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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**5. Claims 25-28, 34, 35, 38, 49, and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaji 6,142,931.**

6. With respect to claims 25, 26, 34, 35, 38, 49, 50, and 52, Kaji discloses an anoscope 1 (fig. 14A), comprising a first hollow body 3 open at opposite ends A,B and a second hollow body 4 open at opposite ends C,D shaping coupled with said first hollow body 3 and arranged to coaxially rotate inside said first hollow body 3, said second hollow body 4 being provided with a window 32 arranged to make a portion 34 of rectal mucous membrane accessible, wherein said window 32 comprises an operating window and has dimensions and a shape such as to enable a surgical device 38 to intervene on said portion (figs. 4-7, col. 7, lines 20-67, cols. 8-16, lines 1-67). Kaji further discloses an angular positioning element 6,9 arranged to adjust the relative angular position of said second hollow body 4 in said first hollow body 3 (via 3) in present reciprocal angular positions 54 (figs. 1B,8B), wherein said second hollow body 4 comprises a rotation segment 25 and an operating segment 4, that can be associated with one another before use, wherein said window 32 is arranged on said operating segment 4, wherein said window 32 opens near to the point that can be reached by the tip of an index finger of a hand of an individual of medium build, by inserting said index finger inside said second hollow body 4 via 33, wherein the opening window 32,33 is of constant size, wherein the window is positioned beyond the distal end of the first hollow body 3 (towards the proximal direction). Kaji further discloses the method for treating hemorrhoids based on the "Sias" method, using the anoscope 1.

7. With respect to claims 27, 28, and 51, an anoscope 1 (fig. 14A) comprising a first hollow body 3 open at opposite ends A,B (see inserted image 1 below) and a second hollow body 4 open at opposite ends C,D shapingly coupled with said first hollow body 3 and arranged to coaxially

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rotate inside said first hollow body 3 via 6,9, said second hollow body 4 being provided with a window 32 arranged to make a portion 34 of rectal mucous membrane accessible, wherein an angular positioning element 6,9 is furthermore provided arranged to adjust the relative angular position of said second hollow body 4 in said first hollow body 3 in preset reciprocal angular positions 54 (figs. 1B,8B), said reciprocal angular positions 54 corresponding to a same number of positions that can be taken up by said window 32 (col. 7, lines 20-67, cols. 8-16, lines 1-67), Wherein said window 32 has dimensions and a shape such as to enable a surgical device 38 to intervene on said portion 34 (figs. 4-10), wherein the preset angular positions correspond to arterial branches of a patient's rectal wall.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaji 6,142,931.**

10. Kaji discloses the invention as discussed above. With respect to the recitation "said operating window is defined by a U-shaped cut" it would have been obvious to one of ordinary skill in the art at the time of the invention to have defined the window 32 to have been a U-shaped or C-shaped cut to facilitate the insertion of larger surgical instruments as desired, since it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

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**11. Claims 29-33 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaji 6,142,931 in view of Chikama 5,345,926.**

12. With respect to claims 29-32, Kaji discloses the invention as discussed above. Kaji further discloses said first hollow body has an edge 6. However, Kaji fails to positively disclose said first hollow body comprises a first truncated-cone portion, wherein said first truncated-cone portion is solidly connected with a second truncated-cone portion that has a progressively decreasing cross-section, wherein said second truncated-cone portion is solidly connected with a third truncated-cone portion that protrudes from a part opposite said first truncated-cone portion and has a progressively decreasing cross-section, wherein said edge is comprised in a base of said first truncated-cone portion.

13. Chikama teaches a first hollow body A,B in an analogous medical observation instrument, said first hollow body comprising a first truncated-cone shaped portion 23, wherein said first truncated-cone portion 23 is solidly connected with a second truncated-cone portion 21C,121X that has a progressively decreasing cross-section, wherein said second truncated-cone portion 21C,121X is solidly connected with a third truncated-cone portion 22 that protrudes from a part opposite said first truncated-cone portion 23 and has a progressively decreasing cross-section (figs. 2,5), wherein said first hollow body has an edge that is comprised in a base of said first truncated-cone portion 23, resulting in an improved medical device which an observation sleeve that is disposable and in which the observation sleeve is supported in a stable manner (col. 2, lines 11-13).

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the anoscope of Kaji with the above discussed limitations as taught by Chikama

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in order to have provided an improved vaginal speculum having an observation sleeve that is disposable and in which the observation sleeve is supported in a stable manner and yet can be discarded quickly after use, which guarantees reliable and safe use of the speculum while facilitating quick and efficient turn around of an operating room after surgery has been completed.

15. With respect to claims 33 and 39-43, Kaji in view of Chikama discloses the invention as discussed above. Kaji further teaches said second hollow body 4 comprises a rotation segment 25 and an operating segment 4, that can be associated with one another before use via 6 (col. 8, lines 19-22, 49-50, 58-61), wherein said edge 6 comprises a plurality of notches 54 (figs. 1B,8B), wherein said notches 54 are 6 in number (figs. 1B,8B), wherein said notches 54 are arranged along said edge 6 according to the hours on an imaginary clock-face (figs. 1B,8B), wherein said angular positioning element 9 via 6 is integral with said rotation segment 25.

16. With respect to the recitation “said notches are arranged at 1 o’clock, 3 o’clock, 5 o’clock, 7 o’clock, 9 o’clock, and 11 o’clock, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified edge 6 such that the notches would have been arranged at 1 o’clock, 3 o’clock, 5 o’clock, 7 o’clock, 9 o’clock, and 11 o’clock or at any desired degree or angle desired, since it has been held that rearranging parts of an invention involves only routine skill in the art, In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

**17. Claims 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaji 6,142,931 in view of Chikama 5,345,926 further in view of Kura 5,507,717.**

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18. Kaji in view of Chikama discloses the invention as discussed above. However, Kaji in view of Chikama fails to positively disclose said angular positioning element comprises a plurality of teeth, wherein said plurality of teeth comprises a locking tooth, wherein said locking tooth comprises a recess housing a peg, wherein an elastic element interposed between said peg and the bottom of said recess.

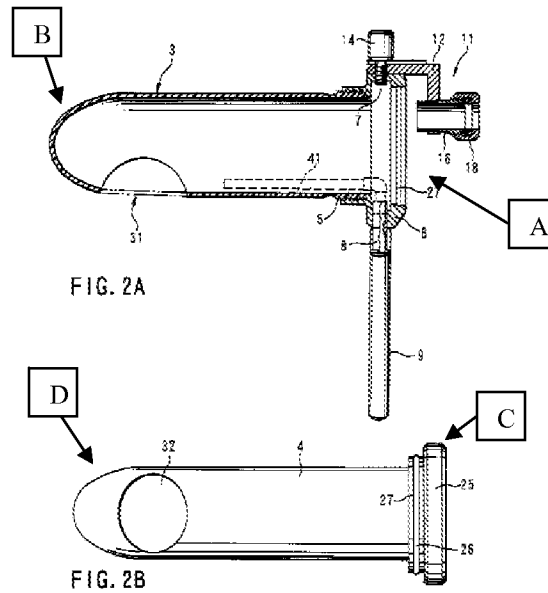
19. Kura teaches an analogous angular positioning element 75 in a similar endoscope device, wherein said angular positioning element 75 comprises a plurality of teeth 325, wherein said plurality of teeth 325 comprises a locking tooth 76, wherein said locking tooth 76 comprises a recess 326,327 housing a peg 80,E via 72 (see inserted image 2 below), wherein an elastic element 328 interposed between said peg 80,E and the bottom of said recess 326,327 (fig. 5, col. 10, lines 61-67, col. 11, lines 1-67), resulting in an advanced medical instrument comprising an improved operation knob that is lighter so that the knob may be easily rotated and removed (col. 1, lines 45-46).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the anoscope of Kaji in view of Chikama with the above discussed limitations as taught by Kura in order to have provided an improved colonoscope comprising an improved operation knob that is lighter and which is easily removed in order to facilitate easy rotation during an operation and which can be easily washed and sterilized.

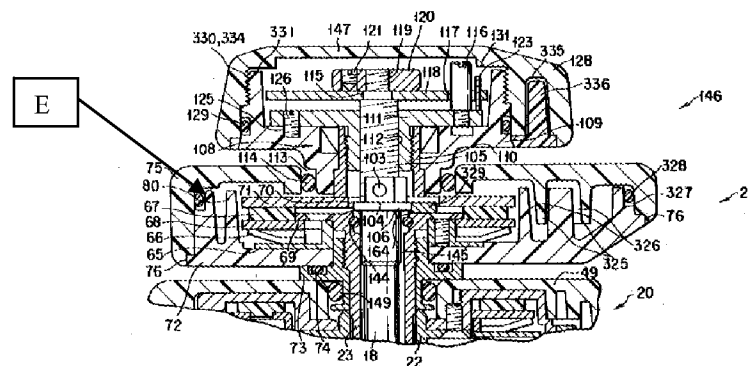


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**Inserted image 1: Figs. 2A and 2B from Kaji US 6,142,931**



**Inserted image 1: Fig. 5 from Kura US 5,507,717**



***Response to Amendment***

21. The amendments to claims 25, 29, 32, 37, and 38, the cancellation of claim 36, and the addition of new claims 49-52 in the response filed on June 12th, 2008 is acknowledged.
22. Claims 25-35 and 37-52 are now pending in the application.

***Drawings***

23. The drawings were received on June 12<sup>th</sup>, 2008. These drawings are of figs. 1-8.

***Response to Arguments***

24. Applicant's arguments with respect to claims 25-48 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. N./

Examiner, Art Unit 3739

Alireza Nia

August 28<sup>th</sup>, 2008

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739